

REMARKS

Applicants respectfully requests reconsideration of the present application in view of the foregoing amendments and the following reasons.

I. Status of the Claims

Claims 3, 23, 24, 37, 41, 45, and 49 were cancelled previously. Claims 1, 30 and 35 have been amended to incorporate the recitations of claim 10, and claim 10 is cancelled. Claims 11, 12, and 54 have been amended to correct dependency.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1, 2, 4-9, 11-22, 25-36, 38-40, 42-44, 46-48, and 50-54 will be pending.

II. Priority Claim

The present application is a continuation-in-part of U.S. Patent Application No. 09/164,351, filed on October 1, 1998, now abandoned. The priority of the '351 application was properly claimed in the New Application Transmittal at page 2, filed on June 22, 1999, the Declaration and Power of Attorney filed on September 20, 1999, as well as in three Application Data Sheets (ADS's) filed on September 5, 2007, March 11, 2010, and April 14, 2010, respectively. However, the Filing Receipt and the U.S. PTO PAIR fails to acknowledge the priority claim to the '351 application.

Applicants file herewith a Request for Corrected Filing Receipt and respectfully request that the Examiner acknowledge the priority claim in the next action.

III. Rejection of Claims under 35 U.S.C. §102(e)

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. §102(e) for alleged anticipation by U.S. Patent Application Publication No. 2007/0048378 by Swanson et al. (“Swanson”). Applicants respectfully traverse the rejection.

Swanson was filed on November 3, 2006 as a continuing application of the present application No. 09/337,675, filed on June 22, 1999, which is a continuation-in-part of U.S. Patent Application No. 09/164,351, filed on October 1, 1998, now abandoned. Therefore, both Swanson and the present application benefit from the same priority date of October 1, 1998. As such, Swanson is not qualified art against the present application under any section of 35 U.S.C. §102. Accordingly, withdrawal of the rejection is respectfully requested.

IV. Rejection of Claims under 35 U.S.C. §103(a)

A. Swanson and Baichwal

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48, and 50-54 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over Swanson in view of US Patent No. 6,093,420 to Baichwal et al. (“Baichwal”). Applicants respectfully traverse the rejection.

As discussed in the foregoing section, Swanson cannot be cited against the present application. Therefore, the rejection should be withdrawn.

B. Liversidge and Baichwal

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,552,160 to Liversidge et al. (“Liversidge”) and Baichwal. Applicants respectfully traverse the rejection.

The Examiner asserts that the claimed invention is obvious over the combined teachings of Liversidge, which allegedly teaches a nanoparticulate NSAID composition, and Baichwal, which allegedly teaches a sustained release dosage form comprising an NSAID. According to the Examiner, it would have been obvious to incorporate the nanoparticulate NSAID composition into Baichwal's sustained release dosage form. *See* Office Action, page 5.

(1) There is no reason that one of ordinary skill in the art would have combined the teachings of the references.

The Examiner contends that Baichwal teaches that uniformly dispersing an NSAID in a polymer matrix is well known in the art, and that Liversidge teaches that nanoparticles can be prepared with well-known carriers. *See* Office Action, at page 5, 3rd full paragraph. At the most, the Examiner is trying to establish that the prior-art elements *could* have been combined. It is unclear, however, why the skilled artisan would have any reason to combine the teachings of the cited art. "It can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

(2) The combined teachings of the references fail to meet the claim recitations.

The combined teachings of Liversidge and Baichwal fail to render the claimed invention obvious. This is because Liversidge is silent as to a controlled release formulation, and Baichwal fails to meet at least the recited high molecular weight rate controlling polymers. More specifically, Baichwal's composition has a "unique dissolution profile, *e.g.*, the initial release of ibuprofen [the active agent] at only 2 hours after in-vitro and the much slower prolonged release of the remaining ibuprofen is caused by the 'swelling' and 'gelling' properties of the xanthan gum and the cross-linking agent upon exposure to an environment fluid." *See* column 5, line 65, through column 6, line 3, of Baichwal. Baichwal further elaborates the possible mechanism of the unique dissolution profile as follows:

...during the initial time period of exposure to an environmental fluid, the xanthan gum hydrates and form a gel matrix causing release of the active agent. As hydration continues, cross-linking of the xanthan gum occurs due to interaction with the cross-linking agent, causing an increase in gel strength and a decrease in the rate of release of drug from the dosage form.

See column 6, lines 10-16, of Baichwal. Clearly, the combination of xanthan gum and the cross-linking agent is crucial to the “unique dissolution profile” of Baichwal’s composition. In contrast, the claimed invention requires the presence of a high molecular weight rate controlling polymer, which is not suggested by Baichwal’s teaching of xanthan gum and a cross-linking agent. Accordingly, the Examiner has not articulated sufficient factual support to establish a *prima facie* case of obviousness.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or

incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By /Michele M. Simkin, Reg. No. 34,717/

FOLEY & LARDNER LLP
Customer Number: 31049
Telephone: (202) 672-5538
Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration No. 34,717